[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-18 10:58:08

Privacy and your personal information

Introduction

1 What is your name?

Name:
[redacted]

2 What is your email address?

Email:
[redacted]

3 What is your organisation?

Organisation:
[redacted]

4 Are you a manufacturer/sponsor/consumer/health care professional?

Other

Refinement 1: Provision of patient information materials

5 Should patient information materials be provided in range of formats including:

Yes

Yes

Yes

Do you agree that the proposed wording of 'made available with' provides clarity for the format of and timing of when PICs and PILs are to be supplied?:

The MyHealth record should be the definitive source record for patients given these are created for all Australians (whether they regularly use them or not). While many older Australians (also generally the recipients of many surgical interventions) may not be savvy with MyHealth records or EMR's in general, there remains a number of weaknesses with reliance on medical cards, including the holding of patient records by device sponsors (will this include a legitimate use, we see this in my opinion abused NOW with insulin pump implant records used to promote replacement of functional devices at 4 year by the sponsors who gain a further sale of over $8K). For reference in my first medical role in 1992 we were providing to surgeon implant cards in Orthopaedics so this is nothing new. I tend to support the concept that the MyHealth record should be the real source of truth, use of cards, referral mechanisms etc all involve increased human effort which also increases breakdown. While it may be a secondary tool, it may not add real value and is more open to abuse.

6 Do you have any other comments/suggestions that we should consider in relation to how PILs and PICs are made available?

Do you have any other comments/suggestions in relation to how Patient Information Leaflets and Patient Implant Cards are to be supplied?:

It should be logical to offer an online source that can be PDF downloaded either by patients or by the clinician in their rooms and provided to the patient, certainly for the PIL ahead of surgery, it is somewhat staggering if this is not already routine practice. As indicated above the cards, represent only a secondary source base to why the MyHealth records system was created. Cards add complexity on how the detail is actually delivered, i.e. by Clinician/Hospital/Device supplier. Again including the device supplier may generate inappropriate promotion of replacement devices as we already see with Medtronic which I strongly object too, where sponsor staff members contact patients and inform them there is a new unit available and that the cost to them is $0 if they have suitable health insurance. In addition to the MyHealth records it may make far more sense that the protocol is changed and the patient receives a scanned copy (hardcopy and digital) of the implant record card. This is far more informative than any card is likely to be and the process already exists, it just requires the inclusion of that data to the patient.

7 As a manufacturer/sponsor/consumer do you foresee any regulatory or cost implications or burden if the PICs and PILs are provided in more than one format?

Do you foresee any cost implications as a manufacturer/sponsor/consumer should the proposed change occur?:

Patient information Literature should be a standard expectation, and the information should be readily accessible on a company website and be able to be downloaded in the doctors rooms, where this is preferred, or downloaded by the patient pre or post visiting the HCP. By contrast I see the cards as

more problematic, two superior sources already exist, the MyHealth records system and the chart stick labels of what is used in the case. The later should be scanned in the patient records and also made available to the patient. This to me is both a superior baseline in terms of data accuracy and reduces the multiple layers of ball passing between hospitals/doctors/sponsors that increase the chance of breakdown. If the GOAL of PICs is so that patients know EXACTLY what is implanted in them then chart stick labels on their records is the best source, if the goal of the PIC is some degree of branding and personal identification then physical cards done graphically make sense (this is what we were producing back in the 1980's for patients to show they had joint replacements when arriving at airport scanners). It seems to me the real intent of this legislation is to be able to record precise device information for records and for patients to have some knowledge of what is implanted in them and know where to look if they need to know more. Assuming that is the case then the MyHealth record with details of the devices used and the chart label meets the needs for HCP's. For a patient to receive on discharge a copy of the chart stick labels, and to know their records is also stored in MyHealth record, and to have been provided a PIL prior to surgery to me would be the gold standard outcome and involve the LEAST movement of information between stakeholders, movement that not only adds cost but increases the risk of information breakdown or further device promotion once warranty periods are exceeded.

Refinement 2: Devices exempt from the requirements of patient information materials

8 Do you agree that it is unnecessary to provide Implant Cards if the device is going to be absorbed by the body within a certain timeframe? Should a PIL still be available?

No

7) Do you agree that devices absorbed within a certain timeframe should be exempt from providing PICs?:

As per my prior comments if patients had access to chart stick labels and these were included in MyHealth then effectively all medical devices implanted are recorded with no need to have multiple cards from multiple suppliers (no doubt the reason that companies like J&J would object to this, as they supply 100's of thousands of these haemostats/tapes today). While it is true most of these items resorb in 6-12 months, particular patients may have physical reactions to foreign body materials and it would help HCP's to register that this may be coming from the shedding material itself. If my suggestion was adopted of patient implant card shared with patient and implanted in their MyHealth record then it does not matter how many or from how many suppliers devices implanted come, workload does not change.

9 If you answered yes to the above question, tell us what would be a reasonable timeframe (e.g. devices absorbed within 3months/6 months), and why?

8) If yes, what is a reasonable timeframe (e.g. 6 months), and why?:

10 If you are a manufacturer, describe the evidence that you could provide to demonstrate that the device will be absorbed within the stated timeframe.

9) If you are a manufacturer, what evidence could you provide to demonstrate that a device is absorbed within a certain timeframe?:

11 Do you agree that it is unnecessary to provide Implant Cards for each pedicle screw, given that many screws could be used in one surgery. Should a PIL still be available? Please explain why?

Yes

Do you agree that an extra 18 month transition period is sufficient to allow the correct provision of PICs for non-exempt, non-sterile implants such as pedicle screws?:

See above response, adopting the patient chart stick label means all implants are recorded for patient. PILs should only really be required for the major components of surgery, in the indication above around pedicle screws, then the sponsor will invariable have information on the pedicle screws and plates/cages in one document. This would then be reinforced post surgery with the chart stick labels. Providing the chart stick labels would also allow patients to observe if devices outside expiry were used on them, an event that today goes under reported.

Other questions

12 Are there any other devices that could have implementation issues which are outside the control of the medical device sponsor and manufacturer? Please give examples.

Are there any other devices that could have implementation issues which are outside the control of the medical device sponsor and manufacturer? Please give examples.:

From my experience in hospitals having seen thousands of surgeries the patient implant report that includes all chart stick labels of devices used remains the best and definitive process for recording what was used, this already exists so the only protocol changes required for recording the implants per patient is to store this in PDF form within patient records, in addition to any other MyHealth segregation or existing recall processes already in place with the TGA/clinicians/hospitals and sponsors. The PIL are appropriate general guidance of items to provide patients at least a broad idea of what will be implanted in them. This remains pertinent after many women impacted by vaginal mesh, reported to having NO idea this was used on them. Having seen hundreds of chart stick labels, these records just carry the sticky labels provided by sponsors with their products and these reports do not have notes written all over them that could create a conflict for patients receiving them directly. There can be no confidentiality aspects or concerns on patients receiving accurate evidence on what actually went into their body!

13 Do you have any other comments in relation to patient information materials?

Do you have any other comments in relation to the above issues around patient information materials?:

By adopting the above suggestion of requiring chart stick labels implant records to ALWAYS be provided to patients on discharge and having these in MyHealth records, will also required greater accountability of hospitals to ensure these are provided and clearly displayed and in turn match to what is actually billed for the patient to final payers be it government, private insurers or other.

Required - Final step - Publishing my response

14 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent:
Yes

15 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response without my name or my organisation's name (anonymously)

16 If there are questions that you don't want published, please indicate those below

If there are questions that you don't want published, please indicate those below:

17 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

18 By making a submission, I acknowledge that:

I acknowledge the above:
Yes